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| APPLICATION NO.              | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|------------------------------|-----------------|----------------------|---------------------|-----------------|
| 10/821,973                   | 04/12/2004      | Tsuyoshi Yamauchi    | YAMAUCH13B          | 3087            |
| 1444                         | 7590 11/04/2005 |                      | EXAMINER            |                 |
| BROWDY AND NEIMARK, P.L.L.C. |                 |                      | BADIO, BARBARA P    |                 |
| 624 NINTH S<br>SUITE 300     | TREET, NW       |                      | ART UNIT            | PAPER NUMBER    |
| WASHINGTON, DC 20001-5303    |                 |                      | 1617                |                 |

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)   |  |  |  |  |
|---|--|--|--|--|--|--|
| Office Action Commence  | 10/821,973   | YAMAUCHI, TSUYOSHI   |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |  |  |  |
|   | Barbara P. Badio, Ph.D.  | 1617   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c   | orrespondence address  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period was Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | i6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on  |  |  |  |  |  |  |
| <u> </u>  | action is non-final.   |  |  |  |  |  |
|   | ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |
| closed in accordance with the practice under E  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |
| Disposition of Claims   |  |  |  |  |  |  |
| 4) Claim(s) 1-13 is/are pending in the application.   | ☐ Claim(s) <u>1-13</u> is/are pending in the application.  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw   | 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
| 6) Claim(s) is/are rejected.  | •  |  |  |  |  |  |
| •   | Claim(s) is/are objected to.   |  |  |  |  |  |
| 8)⊠ Claim(s) <u>1-13</u> are subject to restriction and/or e  | election requirement.  |  |  |  |  |  |
| Application Papers  |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |  |  |  |  |  |  |
| 0) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.   |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex  | aminer. Note the attached Office   | Action or form PTO-152.  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.   |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |  |  |  |  |  |  |
| application from the International Bureau   |  | 3.   |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |  |  |  |  |  |  |
|   |  |  |  |  |  |  |
| Attachment(s)   | _  |  |  |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 4) Interview Summary   |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:   | atent Application (PTO-152)  |  |  |  |  |
|   | ٠, <u> </u>  |  |  |  |  |  |

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### **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1 and 2, drawn to a method of purifying a compound of formula II, classified in class 552, subclass 541.
  - II. Claims 3, 4 and 13, drawn to a compound of formula II or IV, classified in class 552, subclass 541.
  - III. Claims 5-11, drawn to a method of preparing a purified compound of formula I, classified in class 552, subclass 653.
  - IV. Claim 12, drawn to a compound of formula III, classified in class 552, subclass 653.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

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3. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different functions (i.e., a compound and a process).

- 4. Inventions I (II) and III/IV are unrelated because they encompass different compounds.
- 5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-IV, restriction for examination purposes as indicated is proper.

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6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

## Advisory of Rejoinder

7. The following is a recitation of M.P.E.P. §821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02©

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and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565,

37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims

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commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

### Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Parbara Madur Barbara P. Badio, Rh.D. Primary Examiner

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November 1, 2005